AUG 1 6 2002

SECTION 10

510(k) SUMMARY K021650 1 of 2

This 510(k) summary of safety and effectiveness for a modification in the Indications for Use for the Athos Long Pulsed Nd:YAG laser and for two accessories for the Athos laser is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant: Quantel Medical

Address: QUANTEL MEDICAL
21 rue Newton
ZI du BREZET
63039 Clermont-Ferrand
Cedex 2
FRANCE
+33 (0)473 745 745
+33 (0)473 745 700 (Fax)

Contact Person: Mr. Jean Abascal

: (+33) 169 29 17 25
(+33) 169 29 17 29

Preparation Date: April 2002
(of the Summary)

Device Name: Athos laser; Athoscan; Constans Cooling System

Common Name: Nd:YAG Surgical Laser (Long Pulse Nd:YAG laser) and accessories

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology (see: 21 CFR 878.4810).
Product Code: GEX
Panel: 79

Predicate devices: Leg Veins: The HGM VeinLase (K981952); the Altus Family of CoolGlide Lasers (K003202); and Lyra Nd:YAG (K003765; K010834; K990903; and K020463) are cited.

Athoscan: The Hexascan (K890865); SmartScan (K941841); the SoftScan (K971024) the Jenascan (K980001); the Skinscan (K970757); and the Viridis Derma Scanner (K020071) are cited.

Constans Cooling System: The Candela DCD (K951033); the Cynosure Dermatology Laser Cooling Tip (K972002); the Laserscope CoolSpot™ (K984110); the OptoMed, Inc. DermaCool™ (K990417); the EpiLaser Normal Mode Ruby Laser [with cooling] (K963947); and the GentleLase II Dermatology Laser - with DCD and hair removal claims (K984601) are cited.

Device description: The Athos laser emits a beam of coherent light at 1064 microns which is delivered to the Athos handpieces, the Athoscan, or the Constans Cooling System through fiber optics. The Athoscan increases the efficiency of treating large areas of skin (during hair removal) and the Constans Cooling System reduces reduce pain and the risk of thermal damage by cooling the skin during laser treatment.

Indications: The indications for use cleared in K020072 for General Surgery for the Athos laser are modified as follow:

General Surgery: Soft tissue in general surgery applications, skin incisions, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors, lesions, tissue ablation, vessel coagulation, and treatment of leg veins.

The Athoscan and Constans Cooling System are indicated for use with the Athos laser for indications for which the laser has been cleared.

The Athoscan and Constans Cooling System are also labeled: "CAUTION: Federal law restricts the sale to or use by licensed professionals."

Performance Data: None required.

CONCLUSION: Based on the information in this notification Quantel Medical concludes that the Athos laser, with modified indications for use and the Athoscan and Constans Cooling System are substantially equivalent to predicates cited in the notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 6 2002

Quantel Medical
Roger W. Barnes, LTD.
c/o Roger W. Barnes
Regulatory Consultant
342 Sunset Bay Road
Hot Springs, Arkansas 71913

Re: K021650
Trade/Device Name: Athos Laser (Nd:YAG Long-pulsed laser)
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: May 16, 2002
Received: May 20, 2002

Dear Mr. Barnes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 7

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K 0 2 1 6 5 0

Device Name: Athos laser (Nd:YAG Long-pulsed laser) - modification of indications for use and to provide for accessories

Indications for Use Statement:

The General Surgery Indications for Use for the Athos laser are modified as follow:

General Surgery: Soft tissue in general surgery applications, skin incisions, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors, lesions, tissue ablation, vessel coagulation, and treatment of leg veins.

The Athoscan and Constans Cooling System are indicated for use with the Athos laser for indications for which the laser has been cleared.

The Athoscan and Constans Cooling System are also labeled: "CAUTION: Federal law restricts the sale to or use by licensed professionals."

for Mark N Milhem

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021650

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-The Counter Use
(Per 21 CFR 801.109)